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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 10/009,102 | 03/06/2002 | David Watling | 15568.1 | 5518 |

22913 7590 01/09/2006

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EXAMINER

JASTRZAB, KRISANNE MARIE

| | |
|----------|--------------|
| ART UNIT | PAPER NUMBER |
|----------|--------------|

1744

DATE MAILED: 01/09/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|------------------------|---------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 10/009,102 | WATLING, DAVID | |
| | Examiner | Art Unit | |
| | Krisanne Jastrzab | 1744 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 October 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 13-27 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 13-27 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 13-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cummings et al., U.S. patent No. 4,952,370 in view of Childers U.S. patent No. 5,173,258 and Childers U.S. 5,906,794.

Cummings et al., teach sterilization within a sealed enclosure following a flush by sterile, filtered air, wherein a combination of steam and hydrogen peroxide are created in a vaporizer, the combination is then sent to the enclosure and condensed on the surfaces therein. A vacuum is drawn to remove the condensate by evacuation and a purging, sterile, air flow can be initiated as well. The concentration, temperature and pressure parameters within the enclosure are monitored and injection of the steam/hydrogen peroxide is actuated in response thereto. The Cummings et al.,

system is not continuously recirculating. See column 2, lines 40-53, column 3, lines 40-68, column 4, lines 45-62, column 5, lines 20-30, column 6, lines 1-5, 12-16, 20-25, 33-50 and 65-68 and column 7, lines 1-5.

Childers '258 teaches a vapor sterilization process for a sealed enclosure wherein continuous recirculation is applied. Output parameters of temperature, sterilant concentration, pressure and humidity are measured and used to control the input flow. The preferred sterilant is hydrogen peroxide and the carrier gas is air. Means are also provided at the output of the system for the catalytic destruction of any residual hydrogen peroxide. Childers teaches that the use of a recirculating system is easier and less expensive to use because external environmental parameters do not affect the system, and less pressure or vacuum is required to effectively perform the sterilization operation. Childers '258 teaches drying the carrier air to minimize the formation of condensation. See column 4, lines 25-68, column 5 through column 7, line 25, column 8, lines 49-62 and column 9, lines 20-45.

Childers '794 teaches the same system as Childers '258, but that it is not necessary to dry the air in a recirculating system as in '258, and it is, in fact desirable to maintain a saturation level of the sterilant in the system. Childers teaches that this yields superior kill potentials and more efficient sterilization. See column 2, lines 37-55, and column 4, lines 45-50, see also column 5, lines 59-65, column 6, lines 1-68.

It would have been obvious to one of ordinary skill in the art to employ a continuously recirculating flow system in Cummings et al., as taught in both Childers '258 and '794 because it would require minimize the environment affects on system

performance, thereby minimizing equipment requirements and making operation of the system easier, as taught in Childers '258, while still effectively employing a process which is not dry and capable of forming a condensation layer, as taught in Childers '794.

With respect to claims 15-16 and 22, all references teach the use of filtered air.

With respect to claims 17 and 23, both Childers teach control of the monitored gas pressure within the enclosure by air flow.

With respect to claims 26-27, both Childers teach preheating of the carrier gas.

Response to Arguments

Applicant's arguments with respect to claims 13-27 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Hatanaka et al., U.S. patent No. 4,797,255 teach that sterilization by condensation of a thin film of sterilant is known in the art.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

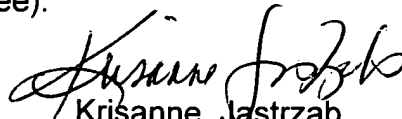
A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not

mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Krisanne Jastrzab whose telephone number is 571-272-1279. The examiner can normally be reached on Mon.-Wed. 6:30am-4:00pm and alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Rick Crispino can be reached on 571-272-1226. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Krisanne Jastrzab
Primary Examiner
Art Unit 1744

January 6, 2006